



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JUN 25 1996

Ms. Katie Huggins  
Manager, Research and Development  
4 Health, Inc.  
5485 Conestoga Court  
Boulder, Colorado 80301

Dear Ms. Higgins:

This is in response to your letter of June 4, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements in the labeling for "Fulfill":

1. Fulfill is a delicious, protein powder meal replacer that:
  - . Replenishes your body with nutrients, including a complete profile of vitamins and an excellent profile of minerals including chromium polynicotinate, a trace mineral which can help your body regulate its blood sugar levels.
  - . Allows you to decrease your daily calorie intake.
  - . Helps satisfy your desire for food and sweets.
2. Take CraveLess and BurnMore, along with Fulfull meal replacer, as part of the TakeCharge Weight Loss System, for optimum results. For weight control, combine the TakeCharge System with exercise and a healthy diet.
3. Take charge of your weight today with Fulfill, the meal replacer that makes you feel better every day.
4. Plus it (Fulfill) contains:  
Our proprietary blend of special ingredients including L-Carnitine, Gugulipid™, Betaine HCL, enzymes and lipotropic factors to provide powerful support in the metabolism of fats.

Our proprietary blend of herbal ingredients including Citrin K™, Gotu Kola Leaf, Milk Thistle Extract, Borage Oil, Chickweed Herb, and Capsicum Fruit to provide support for weight control.

This product does not meet the definition of a dietary supplement in section 201(ff)(2)(B) of the act, which states that a "dietary supplement" is not a food which is represented for use as a conventional food or as a sole item of a meal or the diet. The statements that you are making for "Fulfill" clearly state that the product is intended to be used by persons as a

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meal replacement, in that the claims state that: 1) "Fulfill is a delicious protein powder meal replacer," 2) "Fulfill meal replacer, as part of the TakeCharge Weight Loss System," and 3) "Fulfill, the meal replacer that makes you feel better every day." Because Fulfill is not a dietary supplement under section 201(ff) of the act, it is subject to regulation as a conventional food and must meet the requirements for nutrition labeling, nutrient content claims, and health claims contained in 21 CFR part 101.

We hope this information is helpful.

Sincerely yours,

James Tanner, Ph.D.  
Acting Director, Division of Programs and  
Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition